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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,193	12/07/2005	Geoffrey R. Hill	SPRUS1140 (026470-0501)	9978
30542	7590	03/20/2009	EXAMINER	
FOLEY & LARDNER LLP P.O. BOX 80278 SAN DIEGO, CA 92138-0278			SCHWADRON, RONALD B	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,193	Applicant(s) HILL ET AL.	
	Examiner Ron Schwadron, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-28 and 30 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 24-28,30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____. |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/31/08 and 7/15/08 and 4/2/08.

1. The request to correct the inventorship in this nonprovisional application under 37 CFR 1.48(c) requesting addition of an inventor(s) is deficient because:

The statement of facts by the inventor(s) to be **added does not explicitly state that the amendment of the inventorship is necessitated by amendment of the claims** and that the inventorship error occurred without deceptive intent on the part of the inventor(s) to be added, or cannot be construed to so state (see 1.48(c)(2)).

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 1-7,9-16,18-20,22-28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office action is withdrawn in view of the amended claims and cancellation of claims that have been cancelled.

4. Regarding priority for the amended claims and the application of prior art, claims 24/30 are supported in the priority document whilst claims 25-28 are not. Regarding claims 25-28, whilst the priority document discloses a pharmaceutical composition for *the therapeutic treatment of GVHD* with the ingredients recited in the claims, it does not disclosed the claimed invention without the aforementioned limitation. Regarding claim 28, the priority document discloses a pharmaceutical composition for *the therapeutic treatment of GVHD* with cpn10, an immunosuppressive and a steroid, but does not disclose the claimed invention with just cpn10 and a steroid.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. The rejection of claims 20, 22-26, 28 under 35 U.S.C. 102(b) as being anticipated by Coates et al. (WO 02/40038) for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims and cancellation of claims that have been cancelled.

7. The rejection of claims 16,18-20,22-24 under 35 U.S.C. 102(b) as being anticipated by Morton et al. (US 6,117,421) for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims and cancellation of claims that have been cancelled.

8. The rejection of claims 16,18,20,22,24,29 under 35 U.S.C. 102(a) as being anticipated by Somodevilla-Torres et al. for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims and cancellation of claims that have been cancelled.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. The previous rejection of claims 1-7,9-16,18-20,22-28 under 35 U.S.C. 103(a) as being unpatentable over Morton et al. (US 6,117,421) in view of Kimura et al. for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims and cancellation of claims that have been cancelled.

11. The previous rejection of claims 8,29 under 35 U.S.C. 103(a) as being unpatentable over Morton et al. (US 6,117,421) in view of Kimura et al. as applied to claims 1-7,9-16,18-20,22-28 above, and further in view of Somodevilla-Torres et al. reasons elaborated in the previous Office Action is withdrawn in view of the amended claims and cancellation of claims that have been cancelled.

12. Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morton et al. in view of Kimura et al. and Somodevilla-Torres et al.

Morton et al. disclose in vivo treatment of humans with cpn10 (see claims 8-10). The cpn10 is administered in vivo with a diluent (see column 15, last paragraph). Morton et al. do not disclose the compositions recited in the claims. Morton et al. disclose that cpn10 can be used to promote immunosuppression in a subject to treat graft rejection (see column 6, column 18 and claim 8). The art recognizes that GVHD is caused by transplantation of grafts containing donor lymphocytes including bone marrow (see Kimura et al., page 215, first column). Kimura et al. teach that GVHD can be treated by administering immunosuppressive agents to both the recipient and bone marrow donor (see abstract). The use of cyclosporin and steroids for treatment of graft rejection was well known in the art (for example see Kimura et al., pages 214-215). Somodevilla et al. teach in vivo treatment of a mammal with the cpn10 protein recited in the claims (aka rAla1-101) and the advantages of said form of cpn10 (see entire document). The aforementioned ingredients would have been administered as a pharmaceutical compositions.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed inventions because

Morton et al. disclose that cpn10 can be used to promote immunosuppression in a subject to treat graft rejection whilst Kimura et al. teach that GVHD can be treated by administering immunosuppressive agents to both the recipient and bone marrow donor,

the use of cyclosporin and steroids for treatment of graft rejection was well known in the art and Somodevilla et al. teach in vivo treatment of a mammal with the cpn10 protein recited in the claims (aka rAla1-101). One of ordinary skill in the art would have been motivated to do the aforementioned because Morton et al. disclose that cpn10 can be used to promote immunosuppression in a subject to treat graft rejection whilst Kimura et al. teach that GVHD can be treated by administering immunosuppressive agents to both the recipient and bone marrow donor and the use of cyclosporin and steroids for treatment of graft rejection was well known in the art and Somodevilla et al. teach in vivo treatment of a mammal with the cpn10 protein recited in claim 29 (aka rAla1-101). In addition in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 24-28,30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 12/090821. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Whilst the two sets of claims differ in scope, Seq ID. No. 3 in the claims of 12/090821 is the same sequence as recited in the instant claims. The claims of 12/090821 recite compositions with the ingredients recited in the claims of the instant application and methods of use which use such compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 24-28,30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10,46 of copending Application No. 11/995524. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Whilst the two sets of claims differ in scope, Seq. ID. No. 3 of 11/995524 is the same sequence as recited in the claims of the instant application. The other ingredients recited in the claims were known in the art and would have been obvious to use in a pharmaceutical composition to treat diseases such as those recited in claim 17 of 11/995524.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Primary Examiner, Art Unit 1644